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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,158	01/04/2002	Jan Weber	12013/59401	1766

23838 7590 11/04/2005

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EXAMINER	
STEWART, ALVIN J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,158	WEBER ET AL.	
	Examiner	Art Unit	
	Alvin J. Stewart	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,23 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 30, 2005 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 13-16 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead US Patent 5,116,318 in view of Sahatjian et al US Patent 5,843,089 or Mandrusov et al US Patent 6,660,034 B1 and further view of Yang US Patent 6,544,222 B1.

Hillstead discloses a system comprising: an expandable stent (32), a compliant sheath (40) and an expandable balloon (34). The stent is in contact and crimped over the sheath (see Fig. 4) and the sheath is made of Latex (see col. 4, lines 36-37). The sheath comprises a tube (see Fig. 2) and the tube comprises a length that is greater than the length of the stent (see Fig. 3). Finally, the tube is attached to the balloon at the proximal and distal ends (see Fig. 9 and col. 5, lines 43-45). Additionally Hillstead does not disclose a transparent sheath.

Sahatjian et al discloses a delivery system comprising a catheter, a balloon and a stent. The stent comprises an inner surface having a liner made of hydrogel. The hydrogel is capable of having a therapeutic agent in order to reduce or prevent clotting and/or restenosis at the stent site (see col. 1, lines –55-67 and col. 2, lines 1-31).

Mandrusov et al discloses a stent having a liner and/or a sheath in order to deliver therapeutic substances downstream in the lumen.

Yang discloses a delivery system comprising a stent and a balloon having at least a section which is completely or partially transparent allows for visualization of radiopaque marker bands placed on the catheter shaft (see col. 2, lines 54-67 and col. 3, lines 1-18).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material properties of the stent of the Hillstead or Mandrusov et al reference by adding a coating (with drugs) to the stent in order to reduce or prevent clotting and/or restenosis at the stent site.

Regarding claim 1, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Hillstead reference with the transparent material of the Yang reference in order to allow the visualization of radiopaque marker bands placed on the catheter shaft.

Regarding claims 7, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the end of the compliant sheath of the Hillstead reference because the applicant has not disclosed that by closing about at least one of a distal end of the sheath provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected

Applicant's invention to perform equally well with the two ends of the sheath open (as discloses by the applicant in paragraph 27) because the sheath will greatly reduces, if not completely obviates, the winging effect frequently observed in different balloon catheters (see col. 4, lines 64-68 and col. 5, lines 1-4).

Therefore, it would have been an obvious matter of design choice to modify Hillstead reference to obtain the invention as specified in claim 7.

Regarding claim 24, see Fig. 9.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead US Patent 5,116,318 in view of Sahatjian et al US Patent 5,843,089/Mandrusov et al US Patent 6,660,034 B1 as applied to claim 1 above, and further in view of Yang US Patent 6,544,222 B1 and Hyde et al EP 0553960A1.

Hillstead as modify by Sahatjian and Yang discloses a sheath fixedly attached to the balloon at the proximal and distal ends of the balloon. Hillstead discloses a non-compliant balloon ((38) attached to a compliant sleeve (40) at the proximal and distal ends of each structure (see col. 4, lines 42-46 and Fig. 9). However, Hillstead is silient of how the two structures are attached to each other (does not disclose an adhesive).

Hyde et al discloses a balloon connected to the rest of the catheter by an adhesive or by any mechanical means for the purpose of sealingly connects the two structures together (see col. 6, lines 13-15).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fixation method of the Hillstead reference with the adhesive of the Hyde et al reference in order to sealingly connects the two structures together.

Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead US Patent 5,116,318 in view of Sahatjian et al US Patent 5,843,089 or Mandrusov et al US Patent 6,660,034 B1 as applied to claim 1 above, and further in view Yang US Patent 6,544,222 B1 and Osborn US Patent 5,409,495.

Hillstead as modify by Sahatjian and Yang discloses the invention substantially as claimed. However, Hillstead as modify by Sahatjian do not disclose a lubricant between the balloon and the sheath for the purpose of reducing fiction between structures.

Osborn discloses a catheter having a balloon and a stent. The balloon has a plurality of layers (see Fig. 2) and lubricant. The lubricants are placed between all the interfacing surfaces of the layers (see col. 5, lines 20-25) for the purpose of reducing additional friction and enhance the uniform expansion of the balloon (see col. 5, lines 25-31)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Hillstead reference with the lubricant solution of the Osborn reference in order to reduce the fiction between the structures and enhance the uniform expansion of the balloon.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Stewart

ALVIN J. STEWART
PRIMARY EXAMINER

Art Unit 3738

November 1, 2005.